UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MOLLY F. KULESZ-MARTIN

Appeal No. 2004-1507
Application No. 08/811,361

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claim 11, the only claim pending. Claim 11 reads as follows:

11. A purified peptide designated p53as peptide which peptide is present in p53as protein of a mammal and is identical to the unique carboxy terminal region of p53as which distinguishes p53as protein from p53 protein, said peptide containing a unique epitope which is not present in p53 said peptide containing a peptide sequence selected from the group consisting of SPNC (SEQ. ID #6) and SPPC (SEQ. ID #7).

The references relied upon by the examiner are:

Bowie et al. (Bowie), "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," Science, Vol. 257, pp. 1306-1310 (1990)

Burgess et al. (Burgess), "Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site directed Mutagenesis of a Single Lysine Residue," J. Cell Bio., Vol. 111, pp. 2129-2138 (1990)

Scott et al. (Scott), "The Pendred Syndrome Gene Encodes a Chloride Iodide Transport protein," Nature Genetics, Vol.. 21, pp. 440-443 (1999)

Bork, "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," Genome Research, Vol. 10, pp. 398-400 (2000)

Claim 11 stands rejected under 35 U.S.C. § 101 (utility). We reverse.

Discussion

The claimed invention is directed to a purified peptide designated p53as peptide. The p53 protein is a tumor suppressor. Specification, page 1. The present p53as protein is stated to be "essentially identical" to normal p53 at least until the final 50 amino acids of the carboxy terminal end of the protein and to be an alternatively spliced version of p53. Id., page 2.

The claim on appeal is directed to a purified peptide which is identical to the unique carboxy region of p53as which distinguishes p53as protein from p53 protein. The claimed purified peptide possesses a unique epitope which is not present in p53 and must contain a peptide sequence selected from the group consisting of SPNC and SPCC.

Mouse p53as peptide (SPNC) was used to generate polyclonal antibodies specific to the peptide. Specification, page 14. Mouse p53as peptide was able to

"block binding of p53as antibody but not block the binding [of] other p53 antibodies . . . which bind to epitopes distinct from the unique region of p53as." Id., pages 24-25. Thus, p53as peptide can be used to generate antibodies that distinguish between p53 protein and p53as protein.

The examiner has rejected claim 11 as lacking utility stating "neither the specification nor any art of record teaches what the purified p53as peptide is, how it functions, or a specific and well-established utility for any of the fragments claimed. Furthermore, the specification does not teach a relationship to any specific disease or establish any involvement in the etiology of any specific disease. The asserted utility of the purified p53as protein is based on the assertion that the p53as peptide . . . is structurally similar to mouse and human p53." Examiner's Answer, page 3 (Paper No. 30).

Appellant responds stating "[t]he entire specification is directed to a peptide that permits p53as to be distinguished from p53. The claimed peptide can thus clearly be used to raise an antibody that will react with p53as but will not react with p53. That is sufficient utility under 35 U.S.C. 101 all by itself." Appeal Brief, page 3.

In considering the utility issue raised by the examiner, we note that the examiner has not disputed that p53 is a known tumor suppressor protein. Thus, persons of skill in the art would be interested in qualitatively and/or quantitatively determining the presence of p53. Nor has the examiner disputed that p53as is an alternatively spliced version of p53. Finally, the examiner has not disputed that the polyclonal antibodies to

mouse p53as described by appellant in the specification function to distinguish p53as and p53.

Assuming the examiner's position is correct, i.e., it cannot be assumed that p53as would have the same tumor suppression properties of p53 due to its variant amino acid sequence, we find that the examiner's position supports appellant's case, not the examiner's. Since p53 and p53as share significant amino acid sequence similarity, if one assumes that p53 functions as a tumor suppressor and p53as does not as does the examiner, one would find it useful to be able to distinguish between the two proteins. Thus, the discovery of antibodies that distinguish p53as from p53 would be a useful discovery in that one could determine whether the beneficial p53 or whether non-tumor suppressing p53as is present.

In considering this part of appellant's argument, the examiner states that he is not persuaded because "the use of a protein for the production of an antibody is not considered a specific and or substantial use of a protein. Any protein or epitope once known can be utilized as an antigen for the production of an antibody. The utilization of the protein as an antigen for the production of an antibody only provides the skilled artisan with the starting point from which make [sic] an antibody but does not provide sufficient utility for the protein itself." Examiner's Answer, page 7. However, the examiner's statement does not come to grips with the facts in this case, i.e., the claimed peptide is useful to generate antibodies that distinguish between p53as and p53. Again, assuming the examiner is correct that p53as will not function in the same manner as p53, it would be useful to be able to distinguish the two proteins. The

antibodies described in the present specification that were generated using the claimed peptide provide this function.

The decision of the examiner is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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